

FILED WITH LRC TIME: <u>3 p.m.</u>
AUG 23 2012
Donna Little REGULATIONS COMPILER

## STATEMENT OF EMERGENCY

900 KAR 6:075E

(1) This emergency administrative regulation is being promulgated to implement certain time-sensitive changes to the nonsubstantive review process, including the changes required by the passage of HB458 which establishes the requirements for nonsubstantive review processing of applications for a Certificate of Need by physician owned ambulatory surgical centers when criteria are met. This regulation also includes a change to allow an application for a Certificate of Need to be approved under the nonsubstantive review process when the applicant seeks to provide ambulatory surgery services in an existing ambulatory surgery center (ASC) during times when the ASC is not open and will not charge patients for the service or seek payment from other payers. Last, this regulation allows an application for a Certificate of Need to re-establish a licensed healthcare facility or service when the facility or service was voluntarily discontinued under specific circumstances.

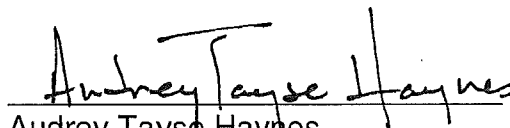
(2) Failure to enact this administrative regulation on an emergency basis will compromise the health, safety and welfare of patients seeking treatment in physician owned ambulatory surgical centers which must seek a Certificate of Need under HB458. Also, offering ambulatory surgery services in an existing ambulatory surgery center during times when the ASC is not open will allow patients who are unable to pay for the services to receive needed ambulatory surgical services immediately.

(3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation to be concurrently filed with the Regulations Compiler.

(4) The ordinary administrative regulation is identical to this emergency administrative regulation.

  
Steven L. Beshear  
Governor

8/23/2012  
Date

  
Audrey Tayse Haynes  
Cabinet for Health and Family Service

8/13/2012  
Date

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:075E. Certificate of Need nonsubstantive review.

5 RELATES TO: KRS 216B.010, 216B.095, 216B.455, 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the  
8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need  
9 Program and to promulgate administrative regulations as necessary for the program.  
10 This administrative regulation establishes the requirements necessary for consideration  
11 for nonsubstantive review of applications for the orderly administration of the Certificate  
12 of Need Program.

13 Section 1. Definitions. (1) "Ambulatory surgical center" is defined by KRS 216B.015.

14 (2) "Cabinet" is defined by KRS 216B.015(5).

15 (3) ~~[(2)]~~ "Certificate of Need Newsletter" means the monthly newsletter that is  
16 published by the cabinet regarding certificate of need matters and is available on the  
17 Certificate of Need Web site at <http://chfs.ky.gov/ohp/con>.

18 (4) ~~[(3)]~~ "Days" means calendar days, unless otherwise specified.

19 (5) ~~[(4)]~~ "Formal review" means the review of applications for certificate of need  
20 which are reviewed within ninety (90) days from the commencement of the review as  
21 provided by KRS 216B.062(1) and which are reviewed for compliance with the review

criteria set forth at KRS 216B.040 and 900 KAR 6:070.

(6) ~~[(5)]~~ "Nonsubstantive review" is defined by KRS 216B.015(17).

(7) ~~[(6)]~~ "Public information channels" means the Office of Communication and Administrative Review in the Cabinet for Health and Family Services.

(8) ~~[(7)]~~ "Public notice" means notice given through:

(a) Public information channels; or

(b) The cabinet's Certificate of Need Newsletter.

(9) ~~[(8)]~~ "Therapeutic cardiac catheterization outcomes" means in hospital mortality rates, door to balloon time, door to balloon time less than or equal to ninety (90) minutes, Percutaneous Coronary Intervention (PCI) related cardiac arrests and emergency open heart surgeries performed as a result of the PCI.

Section 2. Nonsubstantive Review. (1) The cabinet shall grant nonsubstantive review status to applications to change the location of a proposed health facility or to relocate a licensed health facility only if:

(a) There is no substantial change in health services or bed capacity; and

(b) 1. The change of location or relocation is within the same county; or

2. The change of location is for a psychiatric residential treatment facility.

(2) The cabinet shall grant nonsubstantive review status to applications that propose to establish an ambulatory surgical center pursuant to the conditions specified in KRS 216B.095(7).

(3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant to KRS 216B.095(f), the Office of Health Policy shall grant nonsubstantive review status to an application for which a certificate of need is required if:

1 (a) The proposal involves the establishment or expansion of a health facility or  
2 health service for which there is not a component in the State Health Plan;

3 (b) The proposal involves an application from a hospital to reestablish the number of  
4 acute care beds that it converted to nursing facility beds pursuant to KRS 216B.020(4),  
5 if the number of nursing facility beds so converted are delicensed;

6 (c) The proposal involves an application to relocate or transfer licensed acute care  
7 beds, not including neonatal Level III beds, from one (1) existing licensed hospital to  
8 another existing licensed hospital within the same area development district and the  
9 requirements established in this paragraph are met.

10 1.a. There shall not be an increase in the total number of licensed acute care beds  
11 in that area development district; and

12 b. The hospital from which the beds are relocated delicensures those beds.

13 2. If neonatal Level II beds are relocated or transferred pursuant to this paragraph:

14 a. The receiving hospital shall have an existing licensed Level II or Level III neonatal  
15 unit;

16 b. A minimum of four (4) beds shall be relocated; and

17 c. The relocation shall not leave the transferring hospital with less than four (4)  
18 neonatal Level II beds unless the relocated beds represent all of its neonatal Level II  
19 beds;

20 (d) The proposal involves an application by an existing licensed hospital to:

21 1. Convert licensed psychiatric or chemical dependency beds to acute care beds,  
22 not including special purpose acute care beds such as neonatal Level II beds or  
23 neonatal Level III beds;

1        2. Convert and implement the beds on-site at the hospital's existing licensed facility;

2        and

3        3. Delicense the same number of psychiatric or chemical dependency beds that are

4        converted;

5        (e) The proposal involves an application by an existing licensed hospital providing  
6        inpatient psychiatric treatment to:

7        1. Convert psychiatric beds licensed for use with geriatric patients to acute care  
8        beds, not including special purpose acute care beds such as neonatal Level II beds or  
9        neonatal Level III beds;

10       2. Convert and implement the beds on-site at the existing licensed hospital; and

11       3. Delicense the same number of converted beds;

12       (f) The proposal involves an application to transfer or relocate existing certificate of  
13       need approved nursing facility beds between certificate of need approved nursing  
14       facilities or from a certificate of need approved nursing facility to a proposed nursing  
15       facility and the requirements established in this paragraph are met.

16       1. The selling or transferring facility has a certificate of need nursing facility bed  
17       inventory of at least 250 beds;

18       2. The transfer or relocation takes place within the same Area Development District;

19       3. The application includes:

20       a. A properly completed OHP - Form 9, Notice of Intent to Acquire a Health Facility  
21       or Health Service, incorporated by reference in 900 KAR 6:055; and

22       b. Evidence of the selling or transferring entity's binding commitment to sell or  
23       transfer upon approval of the application; and

1        4. A certificate of need approved nursing facility shall not sell or transfer more than  
2        fifty (50) percent of its certificate of need approved nursing facility beds;

3        (g) The proposal involves an application to establish a therapeutic cardiac  
4        catheterization program and the requirements established in this paragraph are met.

5        1. The applicant is an acute care hospital which was previously granted a certificate  
6        of need to participate in a primary angioplasty pilot project and was evaluated after the  
7        first two (2) years of operation by an independent consultant who determined the  
8        hospital successfully demonstrated good therapeutic cardiac catheterization outcomes.

9        2. The applicant shall document that the nursing and technical catheterization  
10       laboratory staff are experienced and participate in a continuous call schedule.

11       3. The applicant shall document that the catheterization laboratory shall be  
12       equipped with optimal imaging systems, resuscitative equipment, and intra-aortic  
13       balloon pump support.

14       4. The applicant shall document that the cardiac care unit nurses shall be proficient  
15       in hemodynamic monitoring and intra-aortic balloon pump management.

16       5. The applicant shall document formalized written protocols in place for immediate  
17       and efficient transfer of patients to an existing licensed cardiac surgical facility.

18       6. The applicant shall utilize a Digital Imaging and Communications in Medicine  
19       (DICOM) standard image transfer system between the hospital and the backup surgical  
20       facility.

21       7. The applicant shall employ an interventional program director who has performed  
22       more than 500 primary PCI procedures and who is board certified by the American  
23       Board of Internal Medicine in interventional cardiology.

1        8. The applicant shall document that each cardiologist performing the therapeutic  
2 catheterizations shall perform at least seventy-five (75) PCIs per year.

3        9. The applicant shall document the ability to perform at least 200 interventions per  
4 year, with ideal minimum of 400 interventions per year by the end of the second year of  
5 operation.

6        10. The applicant shall participate in the American College of Cardiology National  
7 Cardiovascular Data Registry quality measurement program.

8        11. The applicant shall report therapeutic cardiac catheterization data annually to  
9 the Cabinet for Health and Family Services.

10       12. The application shall document the applicant's ability to produce therapeutic  
11 cardiac catheterization outcomes which are within two (2) standard deviations of the  
12 national means for the first two (2) consecutive years; or

13       (h) The proposal involves an application to transfer or relocate existing certificate of  
14 need approved nursing facility beds from one (1) long-term care facility to another long-  
15 term care facility and the requirements established in this paragraph are met.

16       1. The selling or transferring facility fails to meet regulations promulgated by the  
17 Centers for Medicare and Medicaid Services at 42 C.F.R. 483.70(a)(8) requiring nursing  
18 facilities to install sprinkler systems throughout their buildings;

19       2. The selling or transferring facility may sell or transfer portions of its total bed  
20 component to one (1) or more existing nursing facility;

21       3. The facility acquiring the beds shall be located in a county contiguous to that of  
22 the selling or transferring facility;

23       4. The selling or transferring facility shall be licensed only for nursing facility beds at

1 the time of transfer or application to transfer and shall not sell or transfer more than  
2 thirty (30) of its licensed nursing facility beds to an individual facility; and

3 5. The application shall include a properly completed OHP - Form 9, Notice of Intent  
4 to Acquire a Health Facility or Health Service, incorporated by reference in 900 KAR  
5 6:055.

6 (i) The proposal involves an application to re-establish a licensed healthcare  
7 facility or service that was provided at the healthcare facility and which was voluntarily  
8 discontinued by the applicant under the following circumstances:

9 1. The termination of voluntary closure of the former healthcare service or  
10 facility:

11 (a) Was not the result of an order or directive by the cabinet, governmental  
12 agency, judicial body, or other regulatory authority:

13 (b) Did not occur during or after an investigation by the cabinet, governmental  
14 agency, or other regulatory authority:

15 (c) Did occur while the facility was in substantial compliance with applicable  
16 administrative regulations and was otherwise eligible for re-licensure:

17 (d) Was not an express condition of any subsequent Certificate of Need  
18 approval; and

19 2. The proposed healthcare service shall be provided within the same  
20 geographic service area as the former healthcare service;

21 3. The proposed healthcare facility shall be located within the same county as  
22 the former healthcare facility and at a single location; and

23 4. The application shall not seek to re-establish any type of bed utilized in the



1 care and treatment of patients for more than twenty-three (23) consecutive hours.

2 (j) 1. The proposal involves an application to establish an ambulatory surgical  
3 center which does not charge its patients and does not seek or accept commercial  
4 Insurance, Medicare, Medicaid, or other financial support from the federal government;  
5 and

6 2. The proposed ambulatory surgical center shall utilize the surgical facilities of  
7 an existing licensed ambulatory surgical center during times the host ambulatory  
8 surgical center is not in operation.

9 (3) If an application is denied nonsubstantive review status by the Office of Health  
10 Policy, the application shall automatically be placed in the formal review process.

11 (4) If an application is granted nonsubstantive review status by the Office of Health  
12 Policy, notice of the decision to grant nonsubstantive review status shall be given to the  
13 applicant and all known affected persons.

14 (5)(a) If an application is granted nonsubstantive review status by the Office of  
15 Health Policy, any affected person who believes that the applicant is not entitled to  
16 nonsubstantive review status or who believes that the application should not be  
17 approved may request a hearing by filing a request for a hearing within ten (10) days of  
18 the notice of the decision to conduct nonsubstantive review.

19 (b) The provisions of 900 KAR 6:090 shall govern the conduct of all nonsubstantive  
20 review hearings.

21 (c) Nonsubstantive review applications shall not be comparatively reviewed but may  
22 be consolidated for hearing purposes.

23 (6) If an application for certificate of need is granted nonsubstantive review status by

1 the Office of Health Policy, there shall be a presumption that the facility or service is  
2 needed and applications granted nonsubstantive review status by the Office of Health  
3 Policy shall not be reviewed for consistency with the State Health Plan.

4 (7) Unless a hearing is requested pursuant to 900 KAR 6:090, the Office of Health  
5 Policy shall approve each application for a certificate of need that has been granted  
6 nonsubstantive review status if:

7 (a) The application does not propose a capital expenditure; or

8 (b) The application does propose a capital expenditure, and the Office of Health  
9 Policy finds the facility or service with respect to which the capital expenditure proposed  
10 is needed, unless the cabinet finds that the presumption of need provided for in  
11 subsection (6) of this section has been rebutted by clear and convincing evidence by an  
12 affected party.

13 (8) The cabinet shall disapprove an application for a certificate of need that has  
14 been granted nonsubstantive review if the cabinet finds that the:

15 (a) Applicant is not entitled to nonsubstantive review status; or

16 (b) Presumption of need provided for in subsection (6) of this section has been  
17 rebutted by clear and convincing evidence by an affected party.

18 (9) A decision to approve or disapprove an application which has been granted  
19 nonsubstantive review status shall be rendered within thirty-five (35) days of the date  
20 that nonsubstantive review status has been granted.

21 (10) If a certificate of need is disapproved following nonsubstantive review, the  
22 applicant may:

23 (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and

1 900 KAR 6:065;

2 (b) Request that the application be placed in the next cycle of the formal review  
3 process; or

4 (c) Seek judicial review pursuant to KRS 216B.115.

900 KAR 6:075

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

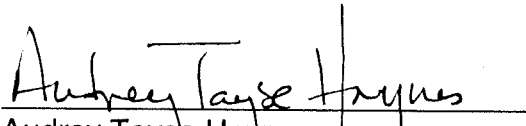
APPROVED:



Carrie Banahan  
Executive Director  
Office of Health Policy

7/12/12  
Date

APPROVED:



Audrey Tayse Haynes  
Secretary  
Cabinet for Health and Family Services

7/13/12  
Date

## REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:075

Contact Person: Carrie Banahan or Chandra Venettozzi, (502) 564-9589

1. Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes the guidelines and considerations for nonsubstantive review of applications for the certificate of need program.
- (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 194A.030, 194A.050, 216B.040(2)(a)1.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 194A.030, 194A.050, 216B.040(2)(a)1 by establishing the considerations for nonsubstantive review of certificate of need applications
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 194A.030, 194A.050, 216B.040(2)(a)1 by establishing the considerations for nonsubstantive review of certificate of need applications.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: The amendment adds language to grant nonsubstantive review status to Certificate of Need applications for ambulatory surgical centers owned by physicians filed pursuant to KRS 216B.095(7), proposed ambulatory surgery centers that will utilize the surgery facility of an existing licensed facility and re-establishment of a licensed healthcare facility or service.
- (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to add language related to physician owned ambulatory surgical centers as a result of the passage of HB 458 in the 2012 Regular Session of the General Assembly. This legislation was signed by the Governor on April 11, 2012.
- (c) How the amendment conforms to the content of the authorizing statutes: The amendment carries out the requirement of KRS 194A.030, 194A.050, 216B.040(2)(a)1, and KRS 216B.095 by establishing the considerations for nonsubstantive review of certificate of need applications.
- (d) How the amendment will assist in the effective administration of the

statutes: This amendment will allow applications submitted by physician owned ambulatory surgical centers, meeting KRS 216B.095 (7) requirements, ambulatory surgery centers providing free services, and previously licensed healthcare facilities seeking re-establishment to be granted nonsubstantive review for a certificate of need.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to file a certificate of need application. Approximately 100 entities file a certificate of need application each year.
4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
  - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: As the considerations for nonsubstantive review of certificate of need applications set forth in the administrative regulation are currently established and operational, no new action will be required of regulated entities to comply with this regulation.
  - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the considerations for nonsubstantive review of certificate of need applications set forth in the administrative regulation are currently established and operational, no cost will be incurred by regulated entities to comply with this regulation.
  - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This administrative regulation will provide potential health care providers with a mechanism to establish health care facilities and services under non-substantive review.
5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
  - (a) Initially: No cost
  - (b) On a continuing basis: No cost
6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing this administrative regulation.
7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if

it is an amendment: No increase in fees or funding is necessary.

8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)  
Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:075    Contact Person: Carrie Banahan or Chandra Venettozzi

1.    What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment may impact any government owned, controlled or proposed healthcare facilities or services as well as the Office of Health Policy within the Cabinet for Health and Family Services.
2.    Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030, 194A.050, 216B.040(2)(a)1.
3.    Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.
  - (a)    How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No impact to revenues.
  - (b)    How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenues will be generated to state or local government.
  - (c)    How much will it cost to administer this program for the first year? None.
  - (d)    How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): None  
Expenditures (+/-): None  
Other Explanation: None